REMARKS

This Amendment is filed in response to the non-final Office Action dated August 26, 2009, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

In the present Amendment, claim 3 has been amended to insert ---substances--- before the phrase "selected from" in line 2 of the claim. No new matter has been added. Entry of the Amendment is respectfully submitted to be proper.

Upon entry of the Amendment, claims 1, 3, 5-12, 14 and 15 are all the claims pending in the application.

I. Response to Rejection Under 35 U.S.C. §112

Claim 3 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Particularly, the Examiner asserts that the phraseology "which further comprises one or more selected from" fails to specify what is being selected (e.g., a substance or a compound, etc.).

Claim 3 has been amended to recite "which further comprises one or more substances selected from." Accordingly, withdrawal of the rejection is requested.

II. Response to Rejection Under 35 U.S.C. § 103

Claims 1, 3, and 5-12 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US 6,608,221 (Toda) in view of US 6,043,223 (Black) or US 2003/0104079 (Sakanaka).

The Examiner asserts that Black describes an infusion preparation of bradykinin that is dissolved in an aqueous solution containing sodium hydroxide and phosphate buffered saline

solution. Per the Examiner, Black further teaches an infusion of bradykinin and 0.09% phosphate buffered saline solution equivalent to a ratio of basic metal ion to bradykinin of 3 to 4 to 1. According to the Examiner, it would have been *prima facie* obvious for a person of ordinary skill in the art to prepare an infusion of a known drug, such as (2R)-2-propyloctanoic acid, comprising a phosphoric acid.

Examiner Sznaidman acknowledges and concedes that the structures disclosed in Black and Sakanaka are structurally different from (2R)-2-propylocatnoic acid. However, the Examiner maintains the above § 103 rejection stating that Black and Sakanaka teach well known infusion processes. The Examiner further asserts that references, such as Nema *et al.*, Akers, and Powell *et al.*, list common excipients and range amounts used for parenteral formulations and indicate that infusions are well known. Therefore, according to the Examiner, absent evidence that the claimed infusion has unexpected properties, the *prima facie* obviousness rejection is maintained.

Applicants respectfully traverse and request that the § 103 rejection be withdrawn in view of the evidence in the Declaration under 37 C.F.R. § 1.132 concurrently submitted herewith, and further in view of the arguments below and the previously submitted arguments filed in the § 116 Amendment filed May 21, 2009.

Regarding evidence of non-obviousness, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.132 executed by Mr. Seiichi Tanikawa, a co-inventor of the presently claimed invention. As indicated in the § 132 Declaration enclosed herewith, the infusion preparation of the present invention makes a water-insoluble (2R)-2-propyloctanoic acid soluble in water and does not require the operation such as dissolution or dilution at the time of use.

Although the cited publications disclose that bradykinin and ginsenoside can be used as an infusion preparation, the remarkable unexpectedly superior effects of the present invention cannot be expected from the cited publications, and therefore the prior art publications do not render the presently claimed invention obvious. Namely, the results show that even if the pH changes as a result of mixing with other pharmaceutical agent, neither clouding nor precipitation occurs.

Further, the stability is excellent. As shown in the data, in the infusion preparation of the present invention, (2R)-2-propyloctanoic is stable. As set forth in the Results section of the § 132 Declaration, the residual ratio of (2R)-2-propyloctanoic is 95% or more after preservation of 48 hours in the infusion preparation of the present invention. Normally, fatty acids such as (2R)-2-propyloctanoic acid, wherein a carbon atom in α-position has a hydrogen atom, tend to show isomerization/racemization by alkalinizing liquid. However, in the infusion preparation of the present invention, it is unexpectedly stable. Accordingly, in view of the unexpectedly superior and remarkable effects of the present claimed invention, Toda in view of Black or Sakanaka do not render the present claimed invention obvious. Therefore, withdrawal of the § 103 rejection based on Toda in view of Black or Sakanaka is respectfully requested.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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